

K964112

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a. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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DEVICE NAME:

Berenstein Coil , Class III

DEVICE DESCRIPTION:

The Berenstein Coil is an occlusion coil designed to be delivered by injection through either Target Therapeutics Infusion Catheters or Balt Magic 1.5F and 1.8F catheters. These coils are radiopaque.

The Berenstein Coil is available in a helical shape, in 0.008 or 0.016 inch primary wind diameter (Berenstein Coil - 10 and Berenstein Coil - 18, respectively), and in a variety of lengths. The Berenstein Coil comes loaded in a sheath-like introducer for easy transfer into a catheter.

An adapter, manufactured by Target Therapeutics, is required when Berenstein Coil - 10 Occlusion Devices are used with Balt Magic catheters. The Adapter may be supplied with the Berenstein Coil or may be available separately.

INTENDED USE:

Berenstein Coils are intended for the embolization of vascular malformations of the peripheral and neuro vasculature.

PREDICATE DEVICES:

The Berenstein Coil is identical in materials, performance, and design parameters to Target Therapeutics Berenstein Coils, cleared for commercial distribution for neuro vascular indications in K961923 and is similar to other Target Therapeutics occlusion coils cleared for use in the peripheral vasculature including